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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/715,184

11/17/2003

George W. Muller

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EXAMINER

HENLEY III, RAYMOND J

ART UNIT

PAPER NUMBER

1614

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/715,184	Applicant(s) MULLER ET AL.	
	Examiner Raymond J. Henley III	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17,24,27-32 and 47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17,24,27-32 and 47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
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| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

CLAIMS 17, 24, 27-32 AND 47 ARE PRESENTED FOR EXAMINATION

Applicants' amendment filed February 13, 2008 has been received and entered into the application.

Applicants' amendments and remarks have overcome the objection to claim 24 and partially the rejection of claims 17 and 24-32 under 35 U.S.C. § 103(a) which rejection and objection is not reiterated herein from the previous Office action.

The rejection and objection not reiterated from the previous office action are hereby withdrawn. Accordingly, such are hereby **withdrawn**. The following rejection is reiterated and contains new grounds of rejection necessitated by Applicants' remarks and/or amendments and constitutes the totality of issues remaining in the present application.

The Examiner appreciates Applicants' attempt to simplify and advance prosecution via the claims amendments and remarks.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejection - 35 USC § 103

Claims 17, 24, 27-32 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muller, (U.S. Patent No. 5,877,200, cited in the IDS filed September 22, 2004 as reference "A53"), of record, for the reasons of record as set forth in the previous Office action dated November 27, 2007 at pages 2-5, as applied to claims 17 and 24-32, which reasons are here incorporated by reference.

In attempting to refute the present presumption of obviousness, Applicants have initially asserted that a *prima facie* case of obviousness has not been established by the Examiner because the present claims are more specific than the teachings of Muller, i.e., “wherein thousands of compounds are described, (Applicants' remarks at page 5, last paragraph). Applicants' basic position here is that the disclosure of Muller is far too broad to render the presently claimed subject matter obvious.

In response, the Examiner takes the position that each and every embodiment of the disclosure of Muller is taught in a manner that one of ordinary skill in the art would have had no problem in their practice. In particular, the compounds are taught as are the diseases. The selection of a particular compound and particular disease are disclosed by Muller in a clear manner allowing the skilled artisan to practice the invention of Muller, however broadly disclosed, in an effective manner. This would include the presently claimed method for treating inflammatory bowel disease and/or Crohn's Disease, specifically disclosed at col. 3, lines 32, 63 and 64, (i.e., Crohn's disease is an inflammatory bowel disease), employing enantiomerically pure 3-(3,4-dimethoxyphenyl)-3-(1-oxo-isoindolin-2-yl)-propionamide, which is specifically disclosed at Example 42 at col. 42 and Examples 105-106 at col. 44.

Applicants further take the position that one skilled in the art would have not been motivated to select the specific compound and specific disease/condition. However, insofar as the specific compound and the specific disease(s) are clearly and unequivocally disclosed, this argument cannot be accepted by the Examiner. Each compound is taught to be effective for each disease, this would have been readily accepted by one of ordinary skill in the art. Nothing

offered by Applicants, expect mere speculation, speaks against the teaching of the reference. Such speculation, however, without more, is not dispositive of a finding of non-obviousness.

Aside from the above, Applicants have further remarked that the claimed subject matter would not have been obvious from the teachings of Muller because the specifically claimed enantiomer's activity would not have been predictable, (remarks at page 6, last paragraph). Applicants have not, however, shown any objective proof that the presently claimed enantiomer provides any therapeutic properties that would not have been expected from the teachings of Muller. As such, the Examiner cannot accept Applicants' position as persuasive of non-obviousness.

Applicants have even further taken the position that one skilled in the art would have had no reasonable expectation of success to arrive at the instantly claimed subject matter in view of Muller, (page 8 of Applicants' remarks). In support of their position, Applicants have offered an "obvious to try" argument, i.e., "To have a reasonable expectation of success, 'one must be motivated to do more than merely 'vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave ... no direction as to which of the may possible choices is like to be successful'",(remarks at page 8).

In response, the Examiner points to Muller's specific and clear teachings that each and every choice of active agent an disease/condition could be effectively treated. Applicants have not provided any showing to the contrary. Mere speculation is not persuasive.

Further, the position that something would have been "obvious to try" and thus is unpatentable has been addressed and dismissed by the Supreme Court in their decision of *KSR International Co. v. Teleflex, Inc., et al.*, 82 U.S.P.Q.2d 1396 as well as the Board decision of Ex

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Parte Smith, --USPQ2d--, slip op. at 20 (Bd. Pat. App. & Interf. June 25, 2007) which is deemed to have foreclosed the idea that that which is "obvious to try" is not patentable.

Finally, Applicants offer that unexpected results have been demonstrated for the presently claimed subject matter, results that would not have been expected from Muller. In particular, Applicants offer that the specifically claimed enantiomer exhibits unobvious, unexpected or superior results in various experiments, (Applicants' remarks at page 9, second full paragraph). In response, it is not seen to be unobvious that one enantiomer exhibits different results than the other enantiomer. One of ordinary skill in the art would have expected that each enantiomer would have exhibited different results such that the totality of results provided by the combination of each enantiomer would have been expected from the results displayed by each enantiomer. Additive results of specific enantiomers, i.e., the activity of the racemic mixture, is not unexpected. To be unexpected, it would first have to be established what one of ordinary skill in the would have expected from each of the enantiomers. This, here, has not been established.

Accordingly, for the above reasons, the claims are deemed to be properly rejected and none are allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Raymond J Henley III
Primary Examiner
Art Unit 1614

March 17, 2008
/Raymond J Henley III/
Primary Examiner, Art Unit 1614